



DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 46

RIN 2900-AR83

Reporting to the National Practitioner Data Bank

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to remove its regulations governing the National Practitioner Data Bank (NPDB). Instead, VA will rely on Department of Health and Human Services (HHS) regulations that govern the NPDB, a Memorandum of Understanding (MOU) between VA and HHS, and VA policy. This change will allow VA to more easily and effectively comply with HHS rules governing the NPDB.

DATES: Comments must be received on or before **[insert date 60 days after the date of publication in the FEDERAL REGISTER]**.

ADDRESSES: Comments may be submitted through www.Regulations.gov.

Except as provided below, comments received before the close of the comment period will be available at www.regulations.gov for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. VA will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any

public comment received after the comment period's closing date is considered late and will not be considered in the final rulemaking.

FOR FURTHER INFORMATION CONTACT: Marianne Chick, MHA, Director, VHA Medical Staff Affairs (10E1F), Office of Quality Management, Department of Veterans Affairs, 810 Vermont Avenue, N.W., Washington, D.C. 20420, Phone (919) 474-3937. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background on the National Practitioner Data Bank

Health Care Quality Improvement Act of 1986 and implementing regulations

The National Practitioner Data Bank (NPDB) was established by the Health Care Quality Improvement Act of 1986 (HCQIA), as amended (42 United States Code (U.S.C.) 11101 et seq.). The NPDB was developed by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), and Bureau of Health Professions (BHP). The NPDB is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions taken against health care practitioners, providers, and suppliers. It is a workforce tool that assists in promoting quality health care and deterring fraud and abuse within health care delivery systems. It prevents health care practitioners, providers, and suppliers from moving from one State to another without disclosure or discovery of previous damaging actions or incompetent performance.

The HCQIA authorizes the NPDB to collect reports of adverse licensure actions against physicians, dentists, and other licensed independent practitioners (including revocations, suspensions, reprimands, censures, probations, and surrenders); adverse clinical privileges actions; adverse professional society membership actions against physicians and dentists; Drug Enforcement Administration (DEA) certification actions; Medicare/Medicaid exclusions; and medical malpractice payments (including settlement

of medical malpractice claims) made for the benefit of any health care practitioner. Information under the HCQIA is reported by medical malpractice payers, State medical and dental boards, professional societies with formal peer review, and hospitals and other health care entities (such as health maintenance organizations). The NPDB reports are confidential and therefore, not accessible by the public. Rather, health care entities that have formal peer review processes and provide health care services, State medical or dental boards, and other health care practitioner State boards have access to this data system. Additionally, individual practitioners may conduct a self-query.

On October 17, 1989, HHS finalized and published the NPDB regulations at 45 CFR part 60. See 54 FR 42722. Those regulations set forth the criteria and procedures for information to be collected in and released from the NPDB, in accordance with the requirements of HCQIA. The NPDB began collecting reports on September 1, 1990. See 55 FR 31239 (August 1, 1990).

VA-HHS Memorandum of Understanding (MOU) and VA regulations

VA and HHS entered into a MOU as required by 42 U.S.C. 11152(b). This MOU was necessary because HCQIA Title IV did not include federal agencies in its reporting and querying requirements. Moreover, as a Federal agency, VA is unable to comply with certain provisions of the HHS regulations regarding reporting procedures and requirements for reporting medical malpractice payments and clinical privileges because certain provisions are governed by the MOU as well as by VA specific policies and procedures.

For instance, consistent with the Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680), Federal District Courts have exclusive jurisdiction over civil actions on claims against the United States, for money damages, due to personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of their office or employment, under circumstances where

the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred. This includes medical malpractice claims filed against a VA medical facility or a VA health care provider. The beneficiary cannot sue the facility or the provider directly but must file the claim against the United States Government. The Federal government assumes responsibility for costs related to a claim resulting from the performance of a medical, surgical, dental, or related function.

Therefore, the MOU addresses reporting payments made by VA for medical malpractice claims, including settlements, made on behalf of a VA health care provider. The MOU includes an agreement that VA will identify the licensed practitioner for whose benefit the payment was made. The MOU also addresses VA's obligation to report: (1) certain actions to State licensing boards; (2) adverse clinical privileging actions against all privileged providers; and (3) actions under Section 1128E of the Social Security Act, which is described in more detail below.

On October 28, 1991, VA published regulations at 38 CFR Part 46 to formalize and interpret the provisions of the MOU. 56 FR 55462. On May 23, 2002, VA subsequently amended this regulation. 67 FR 19678. This amendment reflected changes in VA's internal processes.

Section 1921 of the Social Security Act and implementing regulations

Section 1921 of the Social Security Act (42 U.S.C. 1396r-2), as amended by section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, and the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, expanded the State requirements under the NPDB. Each State is required to adopt a system of reporting to the Secretary of HHS for the following actions: (1) adverse licensure or certification actions taken against health care practitioners, health care entities, providers, and suppliers; and (2) certain final adverse actions taken by State law and

fraud enforcement agencies against health care practitioners, providers, and suppliers. On January 28, 2010, HHS updated its NPDB regulations to comply with Section 1921 of the Social Security Act. See 75 FR 4656. The NPDB began collecting and disclosing section 1921 information on March 1, 2010. 75 FR 4656 (January 28, 2010).

In 1996, the Health Insurance Portability and Accountability Act of 1996, (42 U.S.C. 1320a-7e) added section 1128E to the Social Security Act, which directed HHS to establish and maintain a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken by Federal agencies and health plans against health care practitioners, providers, or suppliers. This data was previously collected by the Healthcare Integrity and Protection Data Bank (HIPDB). The HIPDB began collecting reports in November 1999, but as of May 6, 2013, this collection is now included in the NPDB.¹

Revisions to 45 CFR 60.30 in 2015

On April 5, 2015, HHS amended 45 CFR 60.3 to include VA as a Federal government agency in NPDB reporting requirements. See 78 FR 20473, 20485. We note that the recognition of VA as a Federal government agency does not preclude the need for an MOU between VA and HHS to address circumstances that are not required by the HHS regulations as mentioned above.

II. Proposed removal of 38 CFR part 46

VA has determined, in consultation with HHS, that its NPDB regulations at 38 CFR part 46 should be removed, and that VA should instead rely on HHS regulations at 45 CFR part 60 for NPDB reporting, supplemented with a MOU with HHS and VA policy to address NPDB compliance on issues involving the delivery of health care by a federal

¹ Section 6403 of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148, amended sections 1921 and 1128E to: eliminate duplication between the HIPDB and the NPDB; require the Secretary of HHS to establish a transition period of transferring data collected in the HIPDB to the NPDB; and cease HIPDB operations. Final regulations implementing section 6403 were issued on April 5, 2013 (78 FR 20473) and May 6, 2013 (78 FR 25858).

agency. VA has determined that maintaining separate NPDB rulemaking is problematic. VA's regulations are not comprehensive and therefore, it is not always clear to VA health care professionals, which requirements are applicable.

Since 38 CFR part 46 was drafted to formalize the MOU with HHS, it did not encompass all of VA's required and permissive reporting requirements. For example, additional amendments have been made to the HHS NPDB regulations to include additional reporting requirements that are applicable to VA such as 45 CFR 60.15 and 60.16 78. FR 20473 (April 5, 2013). These amendments require the reporting of exclusions from participation in Federal or State health care programs and other adjudicated actions or decisions. Although required, VA's regulations at 38 CFR part 46 do not explicitly address this requirement. Also, part 46 definitions at 38 CFR 46.1 are not wholly consistent with those found in 45 CFR 60.3. Further, HHS NPDB reporting requirements allow for voluntarily reporting of adverse actions taken against clinical privileges by other health care practitioners. 45 CFR 60.12(a)(2). However, VA did not include this voluntary reporting requirement in its regulation which has precluded it from reporting actions by other health care practitioners. These inconsistencies create confusion and place self-imposed limitations on VA.

In addition, when HHS amends 45 CFR part 60, VA is not able to amend 38 CFR part 46 until after HHS publishes a final rule. VA's NPDB regulation could be inconsistent with HHS's for a significant interim period. This problem is avoided if VA relies on 45 CFR part 60 as guidance on NPDB reporting requirements. In addition, 38 CFR part 46 address internal agency processes related to VA medical malpractice review panels that may be subject to change. Therefore, we believe that it should be memorialized in VA policy rather than regulation.

We note that VA is the only Federal agency providing health care to eligible beneficiaries that published regulations on NPDB compliance. The Department of

Defense has not published regulations on NPDB, but instead cites to 45 CFR part 60 as authority and issued agency policy to implement the NPDB reporting requirements for the component armed services. Likewise, the U.S. Public Health Service and Indian Health Service also issued policies implementing the NPDB reporting requirements.

The proposed removal of 38 CFR part 46 will not obviate VA's reporting requirements nor will it alter how malpractice is handled for VA practitioners. Rather we believe relying on 45 CFR part 60, supplemented by an MOU with HHS and VA policy, will reduce confusion and allow VA to adhere to all mandatory and permissive reporting requirements by eliminating any inconsistency between HHS and VA regulations.

Based on the foregoing rationale, VA proposes removing part 46 and marking it as reserved for future use and relying on HHS regulations at 45 CFR part 60 for NPDB reporting requirements, supplemented by an MOU between HHS and VA policy.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are

defined in the Regulatory Flexibility Act (5 U.S.C. 601-612). This proposed rule would only affect individuals who are VA employees or independent contractors acting on behalf of VA and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. 2 U.S.C. 1532. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Assistance Listing

The Assistance listing numbers and titles for the programs affected by this document are: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; 64.039 CHAMPVA; 64.040 VHA Inpatient Medicine; 64.041 VHA Outpatient Specialty Care; 64.042 VHA Inpatient Surgery; 64.043 VHA Mental Health Residential; 64.044 VHA Home Care; 64.045 VHA Outpatient Ancillary Services; 64.046

VHA Inpatient Psychiatry; 64.047 VHA Primary Care; 64.048 VHA Mental Health Clinics; 64.049 VHA Community Living Center; and 64.050 VHA Diagnostic Care.

List of Subjects in 38 CFR Part 46

Health professions, Reporting and recordkeeping requirements.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on March 27, 2023, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,
Regulations Development Coordinator,
Office of Regulation Policy & Management,
Office of General Counsel,
Department of Veterans Affairs.

For the reasons set forth in the preamble, we propose to amend 38 CFR part 46 as follows:

PART 46 – [Removed and Reserved]

1. Remove and reserve part 46, consisting of § § 46.1 through 46.8.